REMARKS

Claims 1-7, 12 and 31 are pending in the present application. Claims 1, 2, 4 and 12 have been amended. New claims 44, 45 and 46 have been added. Support for the new claims can be found throughout the application as filed. No new matter has been added.

In addition, in response to the Examiner's objection, the title has been amended. The specification has also been amended, at page 140, lines 1 and 2, to recite the ATCC accession number and deposit date.

Claim Objections

The Examiner objected to claims 1, 2 and 12 as reciting non-elected subject matter. The claims have been amended, thereby obviating this objection.

Rejection of Claims 1-7, 12 and 31 Under 35 U.S.C. §101

Claims 1-7, 12 and 31 are rejected under 35 U.S.C. §101 "because the claimed invention is not supported by a credible, substantial, specific or well-established utility." In particular, the Examiner states

> The asserted utilities ... are not considered substantial because the assertion is based mainly on the sequence homology of the human TANGO405 with murine dectin-2, and the tissue origin. Such prediction based upon sequence similarity of known proteins cannot be accepted in the absence of supporting evidence, because it is well known that many proteins belong to the same family, share a high degree of similarity, yet have diverse, and even sometimes opposite biological activities and functions ... Therefore, in the absence of any actual experimental confirmation of any biological properties, the skilled artisan would not accept the asserted utility as being substantial.

Applicants respectfully traverse this rejection. Contrary to the Examiner's assertions the Applicant has provided sufficient evidence to establish that human TANGO 405 is a lectin ortholog of dectin-2 and has similar biological activity to dectin-2. First of all, the human TANGO 405 protein disclosed in the present application has more than just a relatively high

level of sequence homology with dectin-2, it is 89% identical to the amino acid sequence of dectin-2. In addition, Applicants have demonstrated that a translational frameshift in murine TANGO 405 results in an amino acid sequence identical to dectin-2. Furthermore, Applicants have shown that human TANGO 405 is derived from a mixed lymphocyte reaction. This data provides sufficient evidence to establish that human TANGO 405 is a human ortholog of dectin-2 having similar biological activity.

Moreover, Applicants have shown even more than overall sequence identity and tissue origin as alleged by the Examiner. Both human TANGO 405 and dectin-2 have a single C-type lectin domain in the COOH terminus. As shown in figure 4, the C-type lectin domain of human TANGO 405 is about 73% identical to the C-type lectin domain of dectin-2. This is a significantly higher level of identity within the C-type lectin domain of dectin-2 than seen with other C-type lectins. See, e.g., Ariizumi et al. (2000) J. Biol. Chem. 275(16):11957-11963, page 11959 which provides that "the CRD domain in the dectin-2 polypeptide exhibited marked homology with the CDR sequences in other C-type lectins, such as DCIR (44.7%), MGL (43.8%), HL2 (45.8%) ...." In addition, the COOH-terminal region of both dectin-2 and human TANGO 405 contain all thirteen invariant amino acid residues conserved in the C-type lectin domain of many C-lectins. These high levels of sequence identity in a conserved relevant domain of dectin-2 provides further evidence that murine dectin-2 and human TANGO 405 have similar biological function.

In view of the above, it is clear that Applicants have provided sufficient data to establish a substantial credible utility for the claimed nucleic acid molecules. Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

Rejection of Claims 1-7, 12 and 31 Under 35 U.S.C. §112, first paragraph

Claims 1-7, 12 and 31 are rejected under 35 U.S.C. §112, first paragraph. Specifically, the Examiner states that "since the claimed invention is not supported by either a credible

asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention."

Applicants respectfully traverse this rejection. As discussed above in response to the utility rejection, the claimed invention does have a credible asserted utility, and as such one of skill in the art would be able to make and use the claimed invention.

The Examiner further asserts that

> even if the specification taught how to use human TANGO 405, enablement would not be commensurate in scope with claim 1, and the dependent claims 3-7 and 12, which reads on nucleic acids of SEQ ID NO:51 and 52, nucleic acids encoding SEQ ID NO:53 ..., or fragments thereof ..., and variants thereof. ... The specification discloses merely one human gene and its cDNA ... which encodes a polypeptide ..., and provides neither guidance or working examples of any variants of TANGO405. The specification indicates that a fragment of a nucleic acid sequence can be used as a probe, a primer, or to encode a biologically active portion of a polypeptide of the invention. However, the specification does not teach that as a probe, whether these nucleic acid fragments are specific and hybridize only to TANGO 405 polynucleotide, or they may represent parts of conserved regions and hybridize to other members of the family. Further, the specification does not define any domain or region in TANGO 405 as a "biologically active portion", nor, in fact has any specific biological activity been disclosed for TANGO 405. Without knowing what the biologically activity is, it would require undue experimentation to make a fragment conserving such. Additionally, the skilled artisan would not know how to use the fragments which is neither specific to TANGO 405, nor encodes a "biologically active portion.

Applicants respectfully traverse this rejection. The claims as amended no longer recite "naturally occurring variants", thereby obviating the rejection of the claims with regard to variants.

The claims, as amended, recite that nucleic acid molecules include at least 40 consecutive nucleic acid residues of the recited sequence or encode a fragment of a polypeptide having at least 15 consecutive amino acids of the recited sequences. Nucleic acid molecules of these lengths are specific to human TANGO 405, as compared to, e.g., dectin-2. As such, it is clear that under certain stringency conditions, these probes and primers comprising the claimed

nucleic acid fragments would hybridize only to human TANGO 405 polynucleotides. Applicants also disagree with the Examiner's statement that "the specification does not define any domain or region in TANGO 405 ... nor, in fact has any biological activity been disclosed for TANGO 405. This is simply not the case. As discussed above in the response to the utility rejection, Applicants have shown conservation within the sequence of human TANGO 405 and its orthologue dectin-2, including a sufficient amount of identity within the C-type lectin domain. This evidence is sufficient to support that human TANGO 405 has similar biological activity to dectin-2, as is asserted in the specification. Accordingly, Applicants have clearly provided sufficient guidance throughout the specification, to allow one of ordinary skill in the art to make and use the claimed nucleic acid fragments without undue experimentation.

Claims 1, 2 and 12 are also rejected since "the specification fails to provide the deposit statement indicating that the deposit material will be readily available to the public without restriction upon issuance of the patent."

Without conceding the issue, a Declaration of Availability is filed herewith and asserts that human TANGO 405 has been deposited with the ATCC as PTA-424.

Claims 1 and 12 are further rejected under 35 U.S.C. §112, first paragraph "as containing subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention." Specifically, the Examiner asserts that

> The claim limitation of claim 1, part f), and claim 12, part c) is directed to a naturally occurring allelic variant of a polypeptide encoded by SEQ ID NO:51 or 52. The specification discloses SEQ ID NO: 51 and 52, and the putative polypeptide encoded thereby (SEQ ID NO:53). No other variants or species of SEQ ID NO:53 meeting the limitations of these claims were ever identified or particularly described. The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Applicants respectfully traverse this rejection. However, in the interest of expediting prosecution of the present application, the claims have been amended to remove part f of claim 1 and part c of claim 12.

For the reasons discussed above, Applicants respectfully request that this rejection be withdrawn.

Rejection of Claims 1-7, 12 and 31 Under 35 U.S.C. §112, second paragraph

Claims 1-7, 12 and 31 are rejected under 35 U.S.C. §112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

In particular, the Examiner assets that

> claim 1 is indefinite because it is not clear what it is meant by 'comprising an amino acid sequence of ... and the amino acid sequence encoded by ...' in parts c)-f). It does not appear from the specification that the nucleic acids or the polypeptide comprise sequences from multiple SEQ ID Nos or ATCC clones is intended. Claims 2 and 12 are similarly indefinite.

Claim 1 has been amended to indicate in parts d) and e) that the fragment is from an amino acid sequence having the recited sequences. Part f) has been cancelled. With regards to part c), Applicants respectfully traverse that "a nucleic acid molecule which encodes a polypeptide comprising" the recited amino acid sequences is indefinite. Contrary to the Examiner's assertions, the specification clearly indicates that the claimed polypeptides can include more than just the recited sequence. For example, at pages 79 to 81 of the application, Applicants provide that the TANGO 405 polypeptides can be part of a chimeric or fusion protein, and that such fusion proteins can be produced by standard recombinant DNA techniques. Thus, it is clear the claimed invention does contemplate nucleic acid molecules encoding more than just the recited TANGO 405 sequences and that the language in part c) of claim 1 is definite. Therefore Applicants respectfully request that the Examiner withdraw this rejection.

Applicants also submit that the language of claims 2 and 12 is definite. Claim 2 recites a nucleic acid molecule encoding a polypeptide having the recited amino acid sequences. (emphasis added). Claim 12 recites polypeptides of the recited sequences or fragments of polypeptides of the recited sequence. (emphasis added). Thus, the Examiner's assertion that claims 2 and 12 "are similarly indefinite" is misplaced.

Claims 1, 2 and 12 are also rejected "for leaving the ATCC accession numbers blank". The blanks have been removed from the claims, thereby obviating this rejection.

Claim 4 is rejected as being "indefinite because it is unclear what is the structural relationship of the heterologous polypeptide with said polypeptide."

Claim 4 has been amended to indicate that the heterologous polypeptide is a non-TANGO 405 polypeptide. This amendment obviates the Examiner's rejection.

Rejection of Claims 1, 3-7 and 12 Under 35 U.S.C. §102(e) and §102(a)

Claims 1, 3-7 and 12 are rejected under 35 U.S.C. §102(e) "as being anticipated by Ariizuni et al., US 6,046,158" and under 35 U.S.C. §102(a) "as being anticipated by Ariizuni et al., WO 98/28332." According to the Examiner,

> Ariizuni discloses a nucleic acid, SEQ ID NO:3, which encodes a murine dectin-2 protein, and comprises nucleotides 187-212 of SEQ ID NO:52 of the present invention with 100% identity, and nucleic acids encoding amino acids 60 to 71 of SEQ ID NO:53 of the present invention with 100% identity. ... The cited reference, therefore, anticipates claim 1 as being a nucleic acid comprising a nucleotide sequence identical to at least 15 consecutive nucleotide residues of SEQ ID NO:52 ... and a nucleic acid molecule encoding a fragment of at least 10 consecutive amino acid residues of SEQ ID NO:53.

The claims have been amended to recite a nucleic acid molecule comprising at least 40 consecutive nucleotides of the recited nucleotide sequences, or a nucleic acid molecule encoding at least 15 consecutive amino acids of the recited amino acid sequences. Since Ariizuni, U.S. Patent Number 6,046,158 and PCT Publication No: WO 98/28332, do not disclose nucleic acid

molecules comprising at least 40 consecutive amino acids or encoding at least 15 amino acids of the sequences recited in the claims, these references do not anticipate the pending claims.

Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 8/18/03

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